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## ORIGINAL ARTICLE

# Development and validation of the Chinese Overactive Bladder Symptom Score for assessing overactive bladder syndrome in a RESORT study

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## KEYWORDS

bladder diary;  
Chinese;  
overactive bladder;  
questionnaire;  
validation

**Background/Purpose:** This study aimed to develop and validate the Chinese Overactive Bladder Symptom Score (OABSS) for assessing overactive bladder (OAB) symptoms and compare it with a 3-day bladder diary.

**Methods:** The Chinese OABSS was developed by linguistic validation of the original version. Its reliability and validity and correlations with a 3-day bladder diary were tested on patients with OAB in a multicenter study conducted in Taiwan (the RESORT study).

**Results:** A total of 60 patients with OAB, either incontinent (OAB wet,  $n = 31$ ) or continent (OAB dry,  $n = 29$ ), were enrolled consecutively in this study. The test–retest reliability of the Chinese OABSS was moderate to good, with weighted kappa coefficients of 0.515–0.721 for each symptom score and 0.610 for the total symptom score. Each symptom score correlated positively with the total OABSS (Spearman's rho 0.365–0.793) and was internally consistent (Cronbach's alpha 0.674). The distribution of the OABSS showed a clear separation between

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OAB wet (average 11.4, range 7–15) and OAB dry (average 7.97, range 4–10) subgroups (Wilcoxon exact test,  $p < 0.05$ ). In addition, the OABSS items correlated positively with the corresponding bladder diary variables (Spearman's rho 0.504–0.879) and the degrees of agreement improved with study visits except for nighttime frequency. The Chinese OABSS tended to underestimate the frequency of nighttime voiding.

**Conclusion:** The Chinese OABSS has been developed and validated as a reliable instrument for assessing OAB symptoms. OABSS can be an alternative to, but not a replacement for, a 3-day bladder diary for assessing patients.

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## Introduction

Overactive bladder (OAB) syndrome is defined by the International Continence Society as urgency with or without urgency incontinence, usually with frequency and nocturia in the absence of proven infection or other obvious pathology.<sup>1</sup> A subsequent statistical analysis confirmed that urgency is the cornerstone symptom of OAB, and there are at least two distinctive subtypes of OAB, i.e., OAB wet (with urgency incontinence) and OAB dry (without urgency incontinence).<sup>2</sup> OAB, especially OAB wet, has a negative impact on individuals' quality of life, interfering with daily activities, travel, and sleep/vitality.<sup>2,3</sup> Epidemiological studies have demonstrated that the frequency of OAB ranges from 12.4% to 53.1%, depending on the target population and definition of OAB, and the number increases with advancing age.<sup>4–11</sup> OAB syndrome is treated with behavior therapy, electrostimulation, and, most commonly, antimuscarinic agents.<sup>12</sup>

Because OAB is defined by subjective symptoms, rather than objective measures, the patient's perspective is important in managing OAB. To capture the patient's perspective, i.e., symptoms and their impact on quality of life, several patient-reported outcome instruments are available, including the Overactive Bladder Questionnaire (OAB-q), Patient Perception of Bladder Condition (PPBC), Urgency Questionnaire, and the Primary OAB Symptom Questionnaire.<sup>13</sup> However, most of these available measures do not actually evaluate the symptoms of OAB, but rather assess the effects they have on daily life. Although the Overactive Bladder Symptom Composite Score<sup>14</sup> is an exception which can quantify symptoms in a single score, it does, however, require keeping a record in a bladder diary, which limits its range of use.

A bladder diary can provide accurate information about OAB symptoms.<sup>15</sup> However, keeping such a diary can be a burden for patients because they have to keep a diary for several consecutive days, and usually have to carry a reservoir with them at all times in order to measure voided volumes.<sup>16</sup> Previous studies<sup>15,16</sup> have shown that a voiding diary completed for 3–4 days, following detailed instructions, was as reliable and valid for documenting the symptoms of OAB as that kept for 7 days. Therefore, a 3-day bladder diary is usually used.

Recently, Homma et al. have developed and validated a new assessment tool for OAB symptoms, the Overactive Bladder Symptom Score (OABSS). The OABSS total score is the sum of four symptom scores, based on a self-administered questionnaire relating to four areas: daytime frequency, nighttime frequency, urgency, and

urgency incontinence.<sup>17</sup> OABSS evaluates symptoms from the patients' viewpoint and has been demonstrated to have high correlations with corresponding bladder diary variables.<sup>18</sup> OABSS has some advantages over other scales for OAB symptoms, but the disadvantages are that it was written in Japanese and validated using data from Japanese patients only. In order to use OABSS outside Japan, it needs to be translated into the local language and validated based on local patient data.

The present study (RESORT: Reproducibility Study of OABSS and its Response to Treatment) consists two parts to conduct the validation of a traditional Chinese version of the OABSS with Taiwanese patients. Part One is the reproducibility study, which evaluates the reliability and validity of the Chinese OABSS and its correlations with other measures of OAB, including a 3-day bladder diary and PPBC. Part Two, the responsiveness study, compares the Chinese OABSS scores before and after pharmacotherapy with an antimuscarinic agent, solifenacin (5 mg/d). In this manuscript, we report the results for the Part One (reproducibility) study.

## Materials and methods

### Development of Chinese OABSS

A standard linguistic validation process was conducted to ensure conceptual equivalence between the Chinese translations and the original OABSS using the methods described by Acquadro et al.<sup>19</sup>

### Validation of Chinese OABSS

A total of 60 consecutive patients with OAB who visited seven different hospitals in Taiwan were enrolled in this study. A brief protocol including the study calendar and inclusion/exclusion criteria for enrolling patients is shown in Supplement 1.

Patients completed the Chinese OABSS at enrollment and repeated the questionnaire after a nontreatment period of 2 weeks (Part One—the reproducibility study). Patients who took part in Part Two—the responsiveness study—answered the questionnaire again at 4 and 12 weeks after pharmacological treatment with the antimuscarinic agent solifenacin (5 mg/d). Patients also completed a 3-day bladder diary and PPBC at each study visit (a total of four visits). An analysis was conducted to evaluate the reliability and validity of the Chinese OABSS and the correlations with a 3-day bladder diary and PPBC, respectively.

All patients gave informed consent at enrollment and the study protocol was approved by the Joint Institutional Review Board (JIRB) in Taiwan as well as by the institutional review boards at each hospital.

## Statistical analysis

Test–retest reliability of the Chinese OABSS was evaluated by comparison of the variations between the baseline and the 2 weeks' assessment with weighted kappa analysis. The internal consistency of the questionnaire was analyzed using Spearman's rho and Cronbach's alpha. The difference in score distribution between the OAB subgroups was examined using the Wilcoxon exact test. Correlations and agreements between an OABSS item and the corresponding diary variable were examined using the Spearman's coefficient and weighted kappa coefficient, respectively. For this analysis, the corresponding diary variable was converted into the same discrete categories as the OABSS item. The correlations between the OABSS and the PPBC were tested by Spearman's rho.

For interpreting correlation coefficients, the guidelines proposed by Cohen were used, with a coefficient of 0.1 being low, 0.3 being moderate, and 0.5 being high.<sup>20</sup> Kappa coefficients were interpreted using the guidelines provided by Altman as follows: kappa values less than 0.2 represent poor agreement; values of 0.21–0.40, fair agreement; values of 0.41–0.60, moderate agreement; values of 0.61–0.8, good agreement; and values of 0.81–1.00, very good agreement.<sup>21</sup> All statistical tests were two-tailed and conducted with a significance level of 0.05. SAS software (SAS Institute, Cary, NC, USA) was used for statistical computations.

## Results

### Development of Chinese OABSS

The finalized Chinese OABSS is shown in [Supplement 2](#). A pretest was conducted on 15 patients with OAB, who confirmed that the questionnaire was clearly worded, was relevant to patients' complaints, and did not neglect any important symptoms. The questionnaire is a symptom assessment instrument designed to quantify the symptoms of OAB into a single score, and contains questions about the four symptoms of OAB—daytime frequency, nighttime frequency, urgency, and urgency incontinence. Patients were asked to rate their symptom severity during the previous 2 weeks on scales with maximum scores of 2, 3, 5, and 5, respectively. The total score ranged from 0 to 15, and more severe OAB symptoms were indicated by a higher score.

### Validation of Chinese OABSS

A total of 60 patients with OAB, either incontinent (OAB wet;  $n = 31$ ) or continent (OAB dry;  $n = 29$ ), were consecutively enrolled in the study. Each patient answered the questionnaire at time of enrollment and repeated it after a 2-week nontreatment period. Patient characteristics

and the baseline OABSS are shown in [Table 1](#). The average age, body mass index (BMI) values, total OABSS score and "urgency incontinence" symptom score were significantly higher in the OAB wet subgroup than in the OAB dry subgroup as determined by univariate analysis ( $p < 0.05$ ). The other symptom scores were not significantly different between groups.

The Chinese OABSS had moderate to good test–retest reliability with the weighted kappa coefficients ranging between 0.515 and 0.721 for each symptom score and being 0.610 (95% confidence interval 0.488–0.731) for the total symptom score. In addition, tests on the reliability of internal consistency showed that each symptom score correlated positively with the total OABSS score (Spearman's rho 0.365–0.793) and were internally consistent (Cronbach's alpha 0.674). The discriminate validity of the questionnaire was good as it showed a clear separation between the OAB wet (average 11.4, range 7–15) and OAB dry (average 7.97, range 4–10) subgroups (Wilcoxon exact test,  $p < 0.05$ ) ([Fig. 1](#)).

Analysis of the correlations between the questionnaire and a 3-day bladder diary showed that the OABSS items correlated positively with the corresponding bladder diary variables (Spearman's rho 0.504–0.879), and the degree of agreement evaluated by weighted Kappa coefficients improved with study visits (from visit 1 to visit 4) except for nighttime frequency ([Fig. 2](#)). Further analysis indicated that the OABSS tended to underestimate the frequency of nighttime voiding as recorded in a bladder diary. In addition, the Chinese OABSS had only low to moderate correlations with the PPBC (Spearman's rho 0.169–0.313).

We performed a correlation analysis between age and OABSS item and total score. Questions 1 (frequency), 2 (nocturia), and 3 (urgency) did not correlate with age (all  $p > 0.05$ ) but Question 4 (urgency incontinence) and total OABSS score did ( $p < 0.0001$ ). However, there was no significant difference in the OABSS symptom and total score between the male and female subgroups ([Table 2](#)).

## Discussion

Our study results indicated that the questionnaire is as reliable and valid as the original instrument to assess OAB symptoms.<sup>17</sup> However, we also found some differences between the present results and those from previous studies on the original OABSS. One difference is that the correlations between the Chinese OABSS and 3-day bladder diaries were high throughout the study visits; however, the degree of agreement between the two instruments improved to a good level only after the initial concomitant recordings. In contrast, both the correlations and degree of agreement were good at baseline and 12 weeks after treatment in the study conducted by Homma et al.<sup>18</sup> Another difference is that the Chinese OABSS had only low to moderate correlations with the PPBC. In contrast, the correlations were moderate to good in the study conducted by Homma et al.<sup>22</sup>

Homma et al made a comparison between the OABSS and a 3-day bladder diary for assessing OAB symptoms before and after medical treatment. High correlations (Spearman's rho  $\geq 0.5$ ) and a fairly good agreement (kappa

**Table 1** Patient data and symptom scores for the three patient groups.

	Score	OAB	OAB wet	OAB dry
Patients (M/F)	—	60 (14/46)	31 (7/24)	29 (7/22)
Age (y)	Mean $\pm$ SD	55.3 $\pm$ 13.8	61.5 $\pm$ 14.0	48.6 $\pm$ 10.2
	<i>p</i>		OAB wet vs. OAB dry <i>p</i> = 0.000	
Body mass index (kg/m <sup>2</sup> )	Mean $\pm$ SD	24.1 $\pm$ 4.44	25.3 $\pm$ 4.75	22.8 $\pm$ 3.71
	<i>p</i>	—	OAB wet vs. OAB dry <i>p</i> = 0.026	
Question 1	0	1	1	0
Daytime frequency	1	38	19	19
	2	21	11	10
	<i>p</i>	—	OAB wet vs. OAB dry <i>p</i> = 0.868	
	Mean	1.33	1.32	1.35
Question 2	0	5	3	2
Nighttime frequency	1	9	6	3
	2	9	3	6
	3	37	19	18
	<i>p</i>		OAB wet vs. OAB dry <i>p</i> = 0.562	
	Mean	2.30	2.23	2.38
Question 3	0	0	0	0
Urgency	1	0	0	0
	2	2	1	1
	3	8	3	5
	4	18	9	9
	5	32	18	14
	<i>p</i>	—	OAB wet vs. OAB dry <i>p</i> = 0.415	
	Mean	4.33	4.42	4.24
Question 4	0	29	0	29
Urgency incontinence	1	2	2	0
	2	4	4	0
	3	7	7	0
	4	15	15	0
	5	3	3	0
	<i>p</i>	—	OAB wet vs. OAB dry <i>p</i> = 0.000	
	Mean	1.77	3.42	0
OABSS	Range	4–15	7–15	4–10
	<i>p</i>	—	OAB wet vs. OAB dry <i>p</i> = 0.000	
	Mean $\pm$ SD	9.73 $\pm$ 2.60	11.4 $\pm$ 2.28	7.97 $\pm$ 1.57

OAB = overactive bladder; OABSS = Overactive Bladder Symptom Score; SD = standard deviation.

coefficient 0.33–0.80) between changes in OABSS items and the corresponding diary variables were found. The authors suggested that the OABSS could be an alternative to a bladder diary for assessing symptoms and efficacy in daily clinical practice because of the simplicity and dependability of the questionnaire.<sup>18</sup>

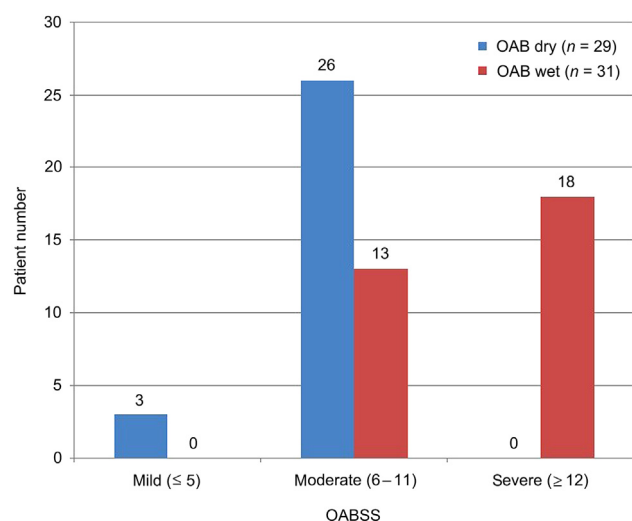
In this study, the Chinese version of the OABSS assessed the voiding condition within previous 2 weeks rather than previous 1 week, as designed by Homma. We chose this longer screening period because we believed 1 week too be too short a time to assess OAB. The symptoms of OAB might occur due to acute conditions such as a small ureteral stone, occult inflammatory pelvic floor disorders, constipation, etc. Since OAB is a chronic bladder condition, the assessment of constant symptoms for 2 weeks seems more reasonable.

In the present study of the Chinese OABSS, we found that the correlations between the two instruments were

high throughout the four study visits, but the degree of agreement improved to a good level after two concomitant recordings at the test–retest study. The results suggested that keeping a diary for 3 days when the Chinese OABSS was administered may have had an educational effect on patients' insight into their bladder conditions, and then an increase in agreement occurred between the two instruments. However, even after several concomitant recordings, the Chinese OABSS still tended to underestimate the frequency of nighttime voiding as recorded in the bladder diaries. This phenomenon is hard to explain but it may be due to the scale pattern used for "nighttime frequency" on the Chinese OABSS or due to the difficulty in patient recall of nighttime voiding.

The PPBC is a validated global measure for OAB and has been shown to have significant correlations with other measures such as bladder diaries and the OAB-q.<sup>23</sup> Homma et al also found OABSS correlated relatively closely with the

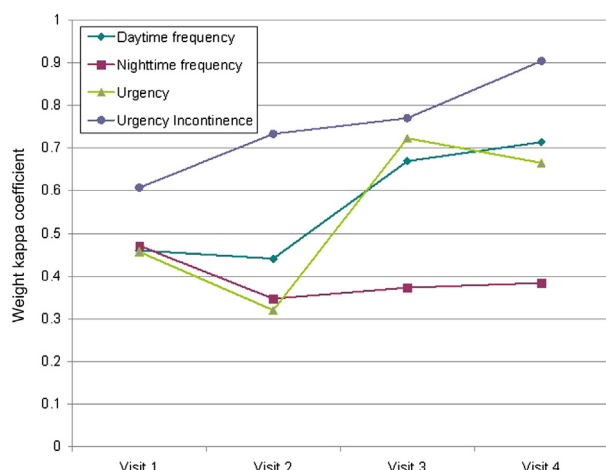




**Figure 1** Distribution of Overactive Bladder Symptom Score (OABSS). OABSS showed a clear separation between OAB wet and OAB dry patients.

PPBC and the OAB-q (Spearman's rho 0.36–0.57).<sup>22</sup> In contrast, the correlations of the Chinese OABSS with the PPBC were low to moderate (Spearman's rho 0.169–0.313) in the present study. We suggest that since the PPBC contains only a single question to evaluate whether patients are bothered by their bladder symptoms, it is subject to daily variations depending on various environmental or personal factors other than their bladder symptoms.

Matza et al have conducted a study to evaluate the test–retest reliability of four patient-reported outcome measures for OAB. The test–retest reliability of the PPBC was somewhat weaker than that for the other three multi-item measures, i.e., the OAB-q, the Urgency Questionnaire, and the Primary OAB Symptom Questionnaire.<sup>13</sup> Therefore, a multi-item disease-specific questionnaire to assess the impact of OAB symptoms on a patient's quality of life may be a better instrument than the PPBC. In future, it would be



**Figure 2** Changes in degrees of agreement (weighted Kappa coefficient) between Overactive Bladder Symptom Score (OABSS) items and the corresponding diary variables at different study visits.

helpful to develop and validate a Chinese version of a quality of life questionnaire with multiple items to pair with the Chinese OABSS for assessing patients.

In the general population, approximately one-third of OAB patients are incontinent (OAB wet).<sup>4–11</sup> However, the number of OAB wet ( $n = 31$ ) and OAB dry ( $n = 29$ ) patients was similar in the present study, which may be due to the higher number of female patients enrolled in this study ( $n = 46$ ; 76.7%). Previous epidemiological studies have shown that, in addition to advancing age and increasing BMI values, female gender is a predisposing factor associated with urgency incontinence in OAB patients.<sup>2,5</sup> In this study, we found similar results to those of previous studies: compared with OAB dry patients, OAB wet patients had significantly higher BMI values, average age, urgency incontinence scores, and total scores on the OABSS (Table 1). However, we did not find a significant difference in OABSS total or single item score between men and women, suggesting that both genders are affected by OAB to similar degrees.

OAB, especially OAB wet, has a negative impact on individuals' quality of life.<sup>3</sup> OAB wet patients also make more adaptive efforts in their daily life than OAB dry patients.<sup>2</sup> Therefore, OAB wet is usually considered to be a severe subtype of OAB. The analysis of the distribution of the total OABSS showed a clear separation between OAB wet and OAB dry subgroups in the present study (Fig. 1) as well as in the study conducted by Homma et al.<sup>17</sup> Therefore, both studies similarly discriminated patients with OAB according to their symptom severity.

Recent epidemiological studies have shown that the prevalence of OAB is similar across the Eastern and the Western world when using the same definition given by the International Continence Society.<sup>6,9–11</sup> However, there is a lower level of public awareness and healthcare-seeking behavior in the East. An early survey on OAB conducted in 11 Asian countries reported that only 21.1% of females and 5.9% of males sought treatment for their OAB.<sup>7,8</sup> Recent surveys conducted in Taiwan<sup>10</sup> and in Japan<sup>9</sup> showed that only 13.0% of Taiwanese and 23% of Japanese individuals whose quality of life was affected by their urinary problems had visited a medical institution for consultation. In contrast, the EPIC study, the largest population survey in five Western countries to date, reported a 60% rate of consultation with a doctor.<sup>6</sup> OAB is an underreported and undertreated condition in the East, especially in Asian countries, which warrants closer attention.

Since the Chinese population is so large, the validated Chinese OABSS could be a very useful clinical tool or research instrument. Due to its simplicity and dependability, we suggest that the Chinese OABSS be used as a tool to screen patients with OAB across the general population to increase public awareness and healthcare-seeking rates in this area. However, one concern is that the Chinese OABSS was developed and validated in Taiwan using Taiwanese patients and traditional Chinese characters. There are, however, many differences between simplified Chinese and traditional Chinese characters. Therefore, the traditional Chinese OABSS cannot be applied directly to other Mandarin-speaking areas; it may only be suitable for the Taiwanese population. In future, it may be necessary to

**Table 2** The difference in OABSS by gender at visit 1.

	Q1	Q2	Q3	Q4	Total OABSS
Male (n = 14)	1.36 ± 0.50	2.21 ± 1.05	4.43 ± 0.76	1.79 ± 2.00	9.79 ± 2.81
Female (n = 46)	1.33 ± 0.52	2.33 ± 1.01	4.30 ± 0.87	1.76 ± 1.86	9.72 ± 2.57
p	0.844	0.721	0.631	0.966	0.932

OABSS = Overactive Bladder Symptom Score.

modify and revalidate the Chinese OABSS if it is to be used in other Mandarin-speaking areas where different dialects and cultural backgrounds exist.

A limitation of this study was the lack of a control group or other disease groups. Moreover, the weighing of the symptom scores of the OABSS is based on epidemiological study conducted in Japan and might not be justified for patients residing outside Japan. Further studies with larger patient numbers, a control group, and other disease groups in Taiwan should be conducted to further validate the Chinese OABSS.

## Conclusion

The Chinese OABSS has been developed and validated as a reliable instrument to assess patients with OAB.

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## Supplementary material

Supplementary material associated with this article can be found, in the online version, at [doi:10.1016/j.jfma.2011.09.020](https://doi.org/10.1016/j.jfma.2011.09.020).

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